REMARKS

Status of the Claims

Claims 1 through 17 are pending. Claims 1 through 17 stand rejected by the Examiner. Claims 1 and 8 have been amended to change "a patient" to recite "the patent" in accordance with the Examiner's suggestion. Claim 8 has been amended to specify the nature of the nervous system injury. Support for this amendment can be found throughout the specification. No claims have are newly added herein by this Amendment. It is believed that no new matter has been introduced by way of the amendments made herein above.

Rejections under 35 U.S.C. §102

Claims 1 through 17 have been rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Steer et al. PCT WO 99/15179. Applicant(s) hereby respectfully traverse(s) this rejection for the following reason(s) as it apples to the pending claims.

The Examiner alleges that PCT WO 99/15179 recites a "method for limiting apoptosis of a mammalian cell population" that the instant claims directed to a "method for treating a patient having a nervous system injury" are anticipated. The Examiner's rejection is premised on the notion that a teaching to a biomechanism necessarily anticipates any methods of treatment involving that biomechanism irrespective of their specificity.

In order for a rejection on anticipatory grounds to be proper, each and every element of Applicants' claims must be found in a single prior art reference. According to MPEP 2131, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Claims 1 and 8 require that the presence of a "patient" and that the "nervous system injury is associated with hemorrhage." PCT WO 99/15179 is absent an express recitation of this element required by Applicants' claims.

"limiting apoptosis" in a "cell population" is not co-extensive in scope with the instantly claimed invention. PCT WO 99/15179 suggests "stroke injury" on pages 16 and 17 within the context of an experiment simulating ischemia. The Examiner is invited to point out where in the PCT WO 99/15179 reference the claim element and limitation pertaining to hemorraghic nervous system injury actually appears. The limitations of Applicants' dependent claims likewise are absent from the reference. It is Applicants' position that the PCT WO 99/15179 reference cannot form the basis of a proper anticipation rejection as the criteria required for a rejection under 35 U.S.C. §102(b) have not been satisfied. Put another way, each and every claim element required by claims 1 through 17 are not present in the reference cited by the Examiner.

Alternatively, the Examiner has asserted that because the recited method claims 1 and 8 make a second reference to "a patient" as opposed to "the patient," the recitation should have no patentable weight to define the invention and thus, does not distinguish the claimed invention from WO99/15179. Applicants have amended claims 1 and 8 so that the second reference to the patient is "the patient" in accordance with the Examiner's recommendation. The Examiner's concerns in this regard have been fully addressed by the amendments made herein, and this rejection should, therefore, be withdrawn.

Given the above, claims 1 through 17 are not anticipated by PCT WO 99/15179 within the proper meaning of 35 U.S.C. §102. This rejection should, therefore, be withdrawn.

Obviousness-Type Double Patenting

Claims 1, 2 through 5, 8 through 12, 15 and 16 have been provisionally rejected by the Examiner based on the judicially created doctrine of non-statutory obviousness-type double patenting. The Examiner applies this rejection based on U.S. Patent No. 6,544,972 and co-pending application Serial No. 10/246,025.

The Examiner alleges that the claims of the instant application are "generic to and anticipated by" claims of Applicants' own Patent No. 6,544,972. Regarding the rejection of claims 1, 3-5, 8 and 10-12 over claims 8-11 of U.S. Patent No. 6,544,972, the discussion in the above response to the Examiner's rejection under 35 U.S.C. §102(b) is likewise applicable here and repeated herein with the induced ischemia appearing in column 10 of the '972 patent. Again, independent claims 1 and 8 require that the presence of a "patient" and that the "nervous system injury is associated with hemorrhage." U.S. Patent No. 6,544,972 is based on PCT WO 99/15179, and is likewise absent an express recitation of this element required by Applicants' claims. Patent No. 6,544,972 claims 8 through 11 directed to a method of "limiting apoptosis" in a "cell population" are not co-extensive in scope with the instantly claimed invention.

Neither are Applicants' claims obvious over claims 8 through 11 of U.S. Patent No. 6,544,972. The Examiner's arguments are premised on a flawed assumption: that experiments simulating brain ischemia/induced ischemia stroke are readily predictive and indicative to one of ordinary skill in the art for treatment of nervous system injuries in general, including hemorrhagic injuries. This is not necessarily the case. According to the Examiner's logic, no experimentation would be necessary to demonstrate or substantiate any methods of treatment *in vivo* if one merely demonstrates a biomechanism *in vitro* since any treatment relating to the biomechanism would be obvious to one skilled in the art.

In essence, the Examiner argues that ischemic stroke and associated apoptosis afford one skilled in the art to conclude that hemorrhagic injury and associated apoptosis can be treated using the same methodology. Contrary to this erroneous view, ischemic stroke is a disease pathophysiologically different from hemorrhagic stroke, even through the term "stroke" is shared

between the two. Ischemic brain injury is due to occlusions of blood vessels in the brain, whereas hemorrhagic brain injury occurs when blood vessels burst. The bursting of blood vessels causes a release of blood directly to cells within the brain, and this direct contact of blood products with neural cells has a toxic effect leading to cell death.

In contrast, the lack of blood flow to the brain associated with ischemic stroke initiates a different cascade of events. Blockage of blood flow causes oxygen deprivation leading to mitochondrial dysfunction. Mitochondria then release caspase c, which in turn initiates apoptosis. Other biochemical pathways are also involved in ischemic brain injury. These include the release of excitotoxic neurotransmitters that cause excessive calcium influx into postsynaptic cells. Excess calcium then overwhelms mitochondria again, leading to apoptosis.

Given the above, one of ordinary skill in the art would not equate a method for treating ischemic stroke injuries in substance or in scope to a method of treating hemorrhagic injury – even if some biological phenomenon may be shared. Applicants' claims and U.S. Patent No. 6,544,972 do not, therefore, provide a proper basis for the obviousness-type double patenting provisional rejection set forth by the Examiner.

The Examiner has also rejected Applicants' claims over certain claims of co-pending Patent Application Serial No. 10/246,025. The Examiner sets forth the following claim sets:

Claims 1 and 8 over claim 30 of co-pending Patent Application Serial No. 10/246,025.

Claims 2 and 9 over claim 36 of co-pending Patent Application Serial No. 10/246,025.

Claims 3 and 10 over claim 31 of co-pending Patent Application Serial No. 10/246,025.

Claims 4 and 11 over claim 32 of co-pending Patent Application Serial No. 10/246,025.

Claims 5 and 12 over claim 33 of co-pending Patent Application Serial No. 10/246,025.

Claim 15 over claim 34 of co-pending Patent Application Serial No. 10/246,025.

Patent Application Serial No. 10/246,025 has been abandoned as of May 11, 2009, which occurred after the Office Action dated March 31, 2009. The provisional rejection set forth by the Examiner is, therefore, moot and the Examiner must now withdraw the rejection.

The Examiner's recommendation of the submission of a Terminal Disclaimer has been noted. Applicants will defer the preparation and submission of such until such time the final appearance of the claims in both the instant application and those of the co-pending application subject to the Examiner's rejection are known.

Conclusion:

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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